

REMARKS

Reconsideration of the above-identified application in view of the amendments above and the remarks following is respectfully requested.

Claims 1-93 are in this case. Claims 1, 2, 12, 13, 27-34, 40-42, 49-57, 60-65, 67, 68, 71-77 and 81 have been rejected under a statutory double patenting rejection (35 USC § 101). Claims 1, 42 and 43 have been rejected under an obviousness-type double patenting rejection. Claims 1, 50, 54, 61, 68, 71, 81 and 84 have been rejected under 35 USC §112 second paragraph. Claims 3-11, 14-26, 35-39, 43-48, 58, 59, 66, 69, 70, 78-80, 82, 83 and 85-93 have been objected to as being dependent on a rejected base claim.

Claims 2, 3, 5, 20, 22, 51-52, 55, 62, 67-68, 74, 80-81, 85 and 88 have now been canceled. Claims 1, 4, 6, 19, 21, 23, 50, 54, 58, 60-61, 65, 69-71, 78 and 82-84 have now been amended. New claims 94-151 have now been added.

Specification

The Examiner has stated that the disclosure is objected to because it is unclear whether the instant application is a divisional, continuation or continuation-in-part of U.S. Patent Application No. 09/802,928 (now U.S. Patent No. 6,562,319).

The paragraph of page 1, lines 13-15, of the instant application has now been amended to recite that the instant application is a continuation-in-part of PCT/IL02/00199, filed March 12, 2002, which is a continuation-in-part of U.S. Patent Application No. 09/802,928.

Applicant believes that this amendment clarifies that the instant application is therefore a continuation-in-part of U.S. Patent Application No. 09/802,928.

Statutory Double Patenting rejection

The Examiner has stated that claims 1, 2, 12, 13, 27-34, 40-42, 49-57, 60-65, 67, 68, 71-77 and 81 are rejected under 35 USC § 101, as claiming the same invention as that of claims 1-4 and 7-40 of prior U.S. Patent No. 6,562,319 and has further stated that these claims are rejected under a double patenting rejection. The Examiner has

suggested that this rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope.

Claims 2, 3, 5, 20, 22, 51-52, 55, 62, 67-68, 74, 80-81, 85 and 88 have now been canceled. Claims 1, 4, 6, 19, 21, 23, 50, 54, 58, 60-61, 65, 69-71, 78 and 82-84 have now been amended. Claims 94-151 have now been added.

U.S. Patent No. 6,562,319 teaches radiolabeled compounds, methods for preparing same and uses thereof in radioimaging and radiotherapy. The compounds disclosed in this patent are represented by the formula I cited therein.

The instant application, however, teaches radiolabeled compounds which are encompassed by formula I of U.S. Patent No. 6,562,319, but presents such compounds that are characterized by novel and advantageous features. These compounds and their beneficial effects are not specifically taught in U.S. Patent No. 6,562,319.

More specifically, in one aspect, the instant application presents radiolabeled compounds having the formula I, in which R³ is a substituted alkyl having 1-6 carbon atoms which comprises a substituted amino group. In another aspect, the instant application presents radiolabeled compounds having formula I, in which either Q1 or Q2 is an alkoxy comprising a morpholino group or an alkylamino comprising a N-piperazinyl group. None of these aspects has been specifically taught in U.S. Patent No. 6,562,319.

Exemplary compounds having general Formula I, in which R³ is a substituted alkyl having 1-6 carbon atoms which comprises a substituted amino group are described in detail in the instant application (see, for example, the preparation of new radiolabeled compounds derived from *N*-{4-[(3,4-dichloro-6-fluorophenyl)amino]quinazoline-6-yl}-4-(dimethylamino)-2-butenamide (Compound 4), *N*-{4-[(3-iodophenyl)amino]quinazoline-6-yl}-4-(dimethylamino)-2-butenamide (Compound 5), *N*-{4-[(3-iodophenyl)amino]quinazoline-6-yl}-4-(methylamino)-2-butenamide (Compound 5a), *N*-{4-[(3-bromophenyl)amino]quinazoline-6-yl}-4-(methylamino)-2-butenamide (Compound 6), described in the Examples section of the instant application). Figures 6-8 present the advantageous performance of these compounds.

Exemplary compounds having the formula I and substituted at the 6 or 7 position of the quinazoline ring by a group containing morpholino or N-piperazinyl are also described in detail in the instant application (see, for example, the preparation of *N*-{4-[(3,4-dichloro-6-fluorophenyl)amino]-7-[3-(4-morpholinyl)propoxy]quinazoline-6-yl} acrylamide (**morpholino- substituted Compound 3**), described in the Examples section). The beneficial effect (e.g., increased bioavailability) of incorporating these groups in the radiolabeled compounds is further described in the instant application (see, for example, page 26, lines 1-11).

In order to overcome the Examiner's rejection, Applicant has chosen to limit the scope of the claimed invention to radiolabeled compounds which include at least one of the above-described novel features, namely, a substituted alkyl that comprises an amino group at R₃ and/or a morpholino/piperazine-containing group at Q1 or Q2.

Hence, independent claims 1, 19, 54, 61, 71 and 84 have been amended to recite a radiolabeled compound having the formula I, in which R³ is a substituted alkyl having 1-6 carbon atoms which comprises a substituted amino group.

Specifically, independent claim 1 has now been amended to recite “[a] radiolabeled compound of a formula I, wherein: ... ***R³ is a substituted alkyl having 1-6 carbon atoms, which comprises a substituted amino group***;

provided that the compound comprises at least one radioactive atom.”.

Claims 3 and 5, which included the limitations now added to amended claim 1, have now been canceled.

Claim 4, which originally depended from claim 3, has now been amended to depend from amended claim 1.

Claim 6, which originally depended from claim 5, has now been amended to depend from amended claim 1.

Claim 19 has been amended to exclude the possibility of R₃ being Hydrogen. Specifically, claim 19 has been amended to recite “[t]he radiolabeled compound of claim 18, wherein each of R¹ and R² is hydrogen”.

Claims 20 and 22, which also included the limitations now added to amended claim 1, have now been canceled.

Claim 21, which originally depended from claim 20, has now been amended to depend from amended claim 19.

Claim 23, which originally depended from claim 22, has now been amended to depend from amended claim 19.

Independent claim 54 has been similarly amended to recite a process of preparing a compound of a formula II "*wherein: ...A, B, C and D are each independently selected from the group consisting of hydrogen and a non-radioactive derivatizing group, ...and R³ is a substituted alkyl having 1-6 carbon atoms, which comprises a substituted amino group; ...*".

Independent claim 61 has been amended to recite a process of preparing a compound of a formula II "*wherein: ...at least one of A, B, C and D is said fluorine-18;...and R³ is a substituted alkyl having 1-6 carbon atoms, which comprises a substituted amino group;*".

Independent claim 71 has been amended to recite a process of preparing a compound of a formula II "*wherein: ... at least one of A, B, C and D is said radioactive bromine or said radioactive iodine;... and R³ is a substituted alkyl having 1-6 carbon atoms, which comprises a substituted amino group; ...*".

Since, as is described in detail in the instant application, the preparation of the radiolabeled compounds encompassed by amended claim 1 (e.g., radiolabeled Compounds 5 and 5a), requires the incorporation of a substituted alkyl to the molecule, claims pertaining to the preparation of the claimed radiolabeled compounds have further been amended to reflect this feature.

Specifically, claim 54 has further been amended to recite "[a] method of synthesizing a radiolabeled compound of a formula II, wherein...the method comprising:

- (a) coupling an aniline derivatized by said R^a, A, B, C and D with a 4-chloroquinazoline substituted at position 6 and/or 7 by at least one reactive group, so as to produce a reactive 4-(phenylamino)quinazoline derivatized by said A, B, C and D; ~~and~~
- (b) reacting said reactive 4-(phenylamino)quinazoline with a reactive carbon-11 labeled α,β -unsaturated carboxylic derivative, said reactive

carbon-11 labeled α,β -unsaturated carboxylic derivative terminating with a second reactive group, so as to produce a carbon-11 labeled 4-(phenylamino)quinazoline substituted by said α,β -unsaturated carboxylic group terminating with said second reactive group; and
 (e) reacting said carbon-11 labeled 4-(phenylamino)quinazoline substituted by said α,β -unsaturated carboxylic group terminating with said second reactive group, with a reactive substituted alkyl having 1-6 carbon atoms."

Claim 61 has now been further amended to recite "[a] method of synthesizing a radiolabeled compound of a formula II, wherein..., the method comprising:

- (a) preparing a fluorine-18 labeled aniline derivatized by said R^a , A, B, C and D, wherein at least one of A, B, C and D is said fluorine-18;
- (b) coupling said fluorine-18 labeled aniline derivatized by said R^a , A, B, C and D with 4-chloroquinazoline substituted at position 6 and/or 7 by at least one reactive group, so as to produce a reactive fluorine-18 labeled 4-(phenylamino)quinazoline derivatized by said A, B, C and D;
and
- (c) reacting said reactive fluorine-18 labeled 4-(phenylamino)quinazoline with a reactive α,β -unsaturated carboxylic derivative, so as to produce a fluorine-18 labeled 4-(phenylamino)quinazoline substituted by an α,β -unsaturated carboxylic group, said reactive α,β -unsaturated carboxylic derivative terminating with a second reactive group, so as to produce a fluorine-18 labeled 4-(phenylamino)quinazoline substituted at position 6 or 7 by an α,β -unsaturated carboxylic group terminating with said second reactive group; and
- (f) reacting said a fluorine-18 labeled 4-(phenylamino)quinazoline substituted at position 6 or 7 by an α,β -unsaturated carboxylic group terminating with said second reactive group with a reactive substituted alkyl having 1-6 carbon atoms."

Claim 71 has now been further amended to recite “[a] method of synthesizing a radiolabeled compound of a formula II, wherein...,the method comprising:

- (a) *coupling an aniline derivatized by said R^a , A, B, C and D, wherein at least one of A, B, C and D is a halogen, with a 4-chloroquinazoline substituted at position 6 and/or 7 by at least one reactive group, so as to produce a reactive 4-(phenylamino)quinazoline derivatized by said A, B, C and D, wherein at least one of A, B, C and D is said halogen;*
- (b) *radiolabeling said reactive 4-(phenylamino)quinazoline derivatized by said A, B, C and D with a radioactive bromine or a radioactive iodine, so as to produce a radioactive bromine labeled or a radioactive iodine labeled reactive 4-(phenylamino)quinazoline derivatized by said A, B, C and D, wherein at least one of said A, B, C and D is said radioactive bromine or said radioactive iodine; and*
- (c) *reacting said radioactive bromine labeled or radioactive iodine labeled reactive 4-(phenylamino)quinazoline with a reactive α,β -unsaturated carboxylic derivative, said reactive α,β -unsaturated carboxylic derivative terminating with a second reactive group, so as to produce a radioactive bromine labeled or radioactive iodine labeled 4-(phenylamino)quinazoline substituted at position 6 or 7 by an α,β -unsaturated carboxylic group terminating with said second reactive group; and*
- (f) *reacting said radioactive bromine labeled or radioactive iodine labeled 4-(phenylamino)quinazoline substituted at position 6 or 7 by an α,β -unsaturated carboxylic group terminating with said second reactive group with a reactive substituted alkyl having 1-6 carbon atoms.”*

Claims 68 and 81, which included the limitations now added to amended claims 61 and 71, have now been canceled.

Claims 69 and 70, which originally depended from claim 68, have now been amended to depend from amended claim 61.

Claims 82 and 83, which originally depended from claim 81, have now been amended to depend from amended claim 71.

Claims 67, 80 and 88, which recited a reactive carboxylic derivative that does not terminate by a reactive group (acryloyl chloride), have also been canceled.

Similarly, claim 60 has been amended to no longer recite acryloyl chloride and to recite 4-bromocrotonyl chloride instead.

In addition, in view of the addition of the limitation "second reactive group" to amended independent claims 54, 61 and 71, claims 58, 65 and 78 have been amended to avoid redundancy of this phrase. Specifically, claims 58, 65 and 78, which originally included the limitation "a second reactive group" with respect to the reactive group at the quinazoline, have now been amended to recite a **third** reactive group.

The Applicant further wishes to note that radiolabeled compounds, in which the radioactive iodine is iodine-131, are also not specifically taught in U.S. Patent No. 6,562,319. Applicant therefore believes that compounds radiolabeled by iodine-131 also present a newly presented feature. Thus, new claim 94, pertaining to a radiolabeled compound as claimed in amended claim 1, in which the radiolabeled iodine comprises iodine-131 has been added. Such iodine-131 labeled compounds are described throughout the instant application (see, for example, pages 29, 36, 49, and 61-64).

In addition to amending/canceling claims 1-93 so as to limit the scope of the claimed compounds, compositions, methods and processes to compounds having formula I and a substituted alkyl that comprises an amino group at R₃, claims pertaining to compounds having formula I, in which Q1 or Q2 comprises a morpholino or a piperazino group have been added. As argued hereinabove, such compounds have not been specifically taught in U.S. Patent No. 6,562,319.

Hence, new claims 95-127, pertaining to compounds as described hereinabove, to compositions containing same, and to methods of radioimaging and radiotherapy using same, have been added. New claims 128-151, pertaining to processes of preparing radiolabeled these compounds have also been added.

Applicant wishes to point out that new claims 128-151 have been written while considering the Examiner's rejections to claims 1-93 set forth in the outstanding Official Action.

It is therefore the Applicant's opinion that amended independent claims 1, 54, 61 and 71, as well as new independent claims 95, 128, 133, 137 and 144, and claims that directly or indirectly depend therefrom are no longer coextensive in scope with claims 1-4 and 7-40 of U.S. Patent No. 6,562,319.

Applicant believes to have overcome the Examiner's statutory double patenting rejection.

Obviousness-type double patenting rejection

The Examiner has stated that claims 1, 42 and 43 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1 and 17 of U.S. Patent No. 6,562,319. Claim 1 has now been amended.

Specifically, the Examiner has stated that although the conflicting claims are not identical, they are not patentably distinct from each other since both sets of claims are directed to radiolabeled compounds of Formula I, wherein the radioactive isotope may be iodine 124.

In view of the Examiner's statutory double patenting rejection above, claim 1 has been amended to recite a compound having Formula I, in which R₃ is a substituted alkyl having 1-6 carbon atoms which comprises a substituted amino group. As is argued hereinabove, amended claim 1 pertains to compounds that were not specifically taught in prior U.S. Patent No. 6,562,319.

Claims 42 and 43, which depend from amended claim 1, therefore also pertain to these newly introduced compounds. It is therefore clear that claims 1 and 17 of the prior patent do not render obvious amended claim 1, as well as claims 42 and 43 which depend therefrom, regardless of the type of iodine radioisotope used, as the issue of the iodine radioisotope is no longer the distinctive feature of these claims.

Applicant therefore believes that amended claim 1, claims 42 and 43, as well as new claim 94, are not rendered obvious in view of claims 1 and 17 of U.S. Patent No. 6,562,319, and hence that a terminal disclaimer is not required.

Similarly, Applicant believes that claims 1 and 17 of the prior patent do not render obvious new independent claim 95 and corresponding claims 117-119, which depend therefrom and hence that a terminal disclaimer is not required with respect to these claims as well.

35 U.S.C. § 112 second paragraph rejections

In one particular, the Examiner has stated that claims 1, 50, 54, 61, 68, 71, 81 and 84 are rejected under 35 USC § 112 second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 68 and 81 have been canceled. Claims 1, 50, 54, 61, 71 and 84 have now been amended.

Specifically, the Examiner has stated that claims 1 (line 21), 54 (line 15), 61 (line 15), 71 (line 15) and 84 (line 15) are ambiguous because the phrase “non radioactive derivatizing group” is unclear. The Examiner has further stated that it is unclear what species Applicant is intending to be compatible with the invention.

The Applicant respectfully wishes to clarify that the term “non-radioactive” is clearly defined in the specification as “*an atom or a derivatizing group that does not comprise a radioactive atom and thus the specific radioactivity thereof is of a background level*” (see page 21, lines 5-9).

Furthermore, the term “derivatizing group” is defined therein as “*a major portion of a group which is covalently attached to another group*” (see page 21, lines 13-15).

Thus, taken together it is clear that any such compatible group can be used in this respect.

Notwithstanding the above, Applicant has chosen, in order to expedite prosecution, to amend claims 1, 54, 61, 71 and 84 to more clearly define the claimed subject matter. Particularly, Applicant has chosen to add to these claims the limitations cited in claims 2, 55, 62, 74 and 85, respectively, as the Examiner has suggested.

Specifically, claim 1 has now been amended to recite “*A radioactive compound of Formula I, wherein ...A, B, C and D are each independently selected*”

from the group consisting of hydrogen, a non-radioactive derivatizing group, and a radioactive derivatizing group, whereas said non-radioactive group is selected from the group consisting of halogen, alkyl, haloalkyl, hydroxy, alkoxy, carboxy, carbalkoxy, thiocarboxy, thiohydroxy, thioalkoxy, alkylsulfinyl, alkylsulfonyl, amino, diamino, carbamyl, dicarbamoyl, nitro and cyano, and said radioactive derivatizing group is selected from a radioactive bromine, a radioactive iodine and a radioactive fluorine;”.

Claims 54, 61, 71 and 84 have been similarly amended.

Claims 2, 55, 62, 74 and 85, which included the limitations now added to claims 1, 54, 61, 71 and 84, have now been canceled.

Applicant therefore believes to have overcome the Examiner's rejection in this respect.

Applicant wishes to further note that new claims 95, 128, 133, 137 and 144 have been written so as to include the same limitations as in amended claims 1, 54, 61, 71 and 84 with respect to the non-radioactive derivatizing group.

In another particular, the Examiner has stated that claim 50, as written, is ambiguous because it is unclear which nuclear imaging technique or techniques the Applicant is/are claiming to be compatible with the instant invention. Claim 50 has been amended. Claims 51 and 52 have been canceled.

Specifically, claim 50 has been amended to specifically recite positron emission tomography (PET) and single photon emission computed tomography (SPECT) as the nuclear imaging techniques utilized by the claimed method. The Examiner's attention is directed in this respect to the specification of the instant application, in which ample support for the compatibility of these techniques with respect to the claimed invention can be found (see, for example, the description from page 1, line 32 to page 2, line 10, and from page 35, line 27 to page 36, line 21).

Thus, claim 50 has now been amended to recite:

“A method of monitoring the level of epidermal growth factor receptor within a body of a patient, the method comprising:

(a) administering to the patient the radiolabeled compound of claim 1; and

(b) *employing a nuclear imaging technique, selected from the group comprising of positron emission tomography (PET) and single photon emission computed tomography (SPECT), for monitoring a distribution of the compound within the body or within a portion thereof."*

Claims 51 and 52, which included the limitations now added to amended claim 50, have now been canceled.

Applicant believes to have overcome the Examiner's rejection in this respect.

Applicant wishes to further note that new claim 126 has already been written in an allowable form and recites: "*A method of monitoring the level of epidermal growth factor receptor within a body of a patient, the method comprising:*

- (a) *administering to the patient the radiolabeled compound of claim 95;*
and
- (b) *employing a nuclear imaging technique, selected from the group comprising of positron emission tomography (PET) and single photon emission computed tomography (SPECT), for monitoring a distribution of the compound within the body or within a portion thereof."*

Furthering another particular, the Examiner has stated that claims 54 (line 28), 61 (lines 33-34), 68 (lines 2-3) and 81 (lines 2-3), as written are ambiguous with regard to the term "carboxylic derivative" since it is unclear what carboxylic derivative the Applicant is claiming to be compatible with the instant invention. The Examiner has also stated that it is unclear which portion of the parent compound remains in the derivative. Claims 68 and 81 have been canceled. Claims 54 and 61 have been amended.

In response, Applicant wishes to point out that the phrase "carboxylic derivative" is cited in the above-referenced claims in the context of a "*reactive α,β -unsaturated carboxylic derivative*". The term "carboxy" in itself is clearly defined in the specification as a -C(=O)- group (see page 23, line 9). Thus, it would be clear to any person skilled in the art that the term "carboxylic derivative" refers to a derivative containing the -C(=O)- group.

Later on, said "carboxylic group" is exemplified to be an amide, an ester, a hydrazinamide or a ketone (see page 25, lines 1-2). Furthermore, the specification

goes on to indeed describe which carboxylic derivatives are claimed to be compatible with the instant invention, these being “ α,β -unsaturated carboxylic group(s)” (also defined therein as an X-Y(=O)-Z group). The “ α,β -unsaturated carboxylic group” is then defined as any group that comprises a -C(=O)- group and is linked at the distal end thereof to an unsaturated group, which is separately defined as a substituted or non-substituted hydrocarbon that comprises at least two carbon atoms and at least one unsaturated bond, such as alkenyl, alkynyl and diene (see from page 24, line 24 to page 25, line 6).

In addition, the term “reactive” is clearly defined and described as “*a group or derivative which can be easily reacted with another group so as to produce a new compound that comprises a new functional group*”. Representative examples of a reactive group are specified to include nitro, amino, hydroxy, alkoxy and halogen (see, page 30, lines 18-28).

The Examiner's attention is further directed to the description and schemes of the syntheses of the compounds of the claimed invention, where the reactions between the reactive carboxylic derivatives (represented as Z-C(=O)-M and the reactive quinazoline are illustrated (see, for example, scheme 1, and accompanying description on pages 44-47; scheme 2 and accompanying description on pages 47-49; and scheme 3, and accompanying description on pages 49-64).

Hence, a skilled artisan would clearly recognize that a “reactive α,β -unsaturated carboxylic derivative” would be a reactive derivative of any “ α,β -unsaturated carboxylic acid” as defined in the application, wherein the derivative includes the “carboxy” and “ α,β -unsaturated” features of the molecule and the reactive derivative refers to that end of the molecule that participates in the bond formation (as the term “reactive” is defined in the application). Furthermore, a skilled artisan would also know which derivative would be compatible for a given reaction.

Applicant therefore strongly believes that the subject matter of claims 54, 61, 68 and 81 is particularly pointed out and distinctly claimed in this respect and hence that these claims are not ambiguous..

Applicant further believes that the subject matter of new claims 128, 131-133, 137 and 144 is similarly particularly pointed out and distinctly claimed in this respect.

In another particular, the Examiner has stated that claim 71 (lines 40-41), as written, is ambiguous with regard to the term "reactive α,β -unsaturated derivative" since it is unclear what species the Applicant is claiming to be compatible with the instant invention. Claim 71 has now been amended.

Applicant wishes to point out in this respect that it appears that the word "carboxylic" was unintentionally omitted from this claim. Claim 71 should have included the phrase "reactive α,β -unsaturated carboxylic derivative".

Claim 71 has therefore been amended to recite:

"A method of synthesizing a radiolabeled compound of a formula II, ...the method comprising:

- (a) ...;*
- (b) ...*
- (c) reacting said radioactive bromine labeled or radioactive iodine labeled reactive 4-(phenylamino)quinazoline with a reactive α,β -unsaturated carboxylic derivative, said...;and*
- (d) ..."*

The Examiner's attention is directed in this respect to the specification of the instant application, and particularly to the description from page 34, line 27 to page 35 line 15, in which the preparation of radioactive iodine and radioactive bromine labeled compounds (corresponding to the subject matter claimed in claim 71) is described and in which the phrase "reactive α,β -unsaturated carboxylic derivative" is cited.

The Examiner's attention is further referred to the arguments set forth hereinabove, with regard to the non-ambiguity of the phrase "carboxylic derivative".

Applicant therefore strongly believes that the subject matter of amended claim 71 is particularly pointed out and distinctly claimed in this respect and hence that amended claim 71 is not ambiguous.

Claim objections

The Examiner has stated that claims 3-11, 14-26, 35-39, 43-48, 58, 59, 66, 69, 70, 78-80, 82; 83 and 85-93 are objected to as being dependent on a rejected base claim. Claims 2-3, 5, 20, 22, 51-52, 55, 62, 67, 68, 74, 80-81, 85 and 88 have now

been canceled. Claims 1, 4, 6, 19, 21, 23, 50, 54, 58, 60-61, 65, 69-71, 78 and 82-84 have now been amended.

Specifically, the Examiner has stated that these claims would be allowable if rewritten in an independent form including all the limitations of the base claim and any intervening claims.

The limitations of claims 3 and 5 have now been added to amended independent claim 1. Amended claim 1 therefore constitutes an independent form of these claims. Amended claims 4 and 6, as well as original claims 7-18, 27-37, 40-49 and 53, all depend, directly or indirectly, from amended claim 1.

Similarly, the limitations of claims 20 and 22 have now been added to amended claim 19. Amended claim 19 therefore constitutes an independent form of these claims. Amended claims 21 and 23, as well as original claims 24-26 and 38-39, all depend, directly or indirectly, from amended claim 19.

Independent claim 54 and claim 58 have been amended as detailed hereinabove re: the Examiner's statutory double patenting rejection.

Independent claim 61 has been amended to include the limitations of claim 68.

Independent claim 71 has been amended to include the limitations of claim 81.

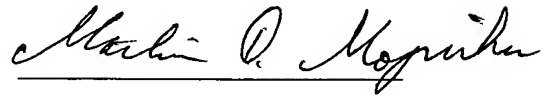
As is argued hereinabove, re: the Examiner's statutory double patenting rejection, Applicant believes that amended independent claims 54, 61 and 71, are allowable.

In addition, Applicant wishes to note that new claim 94 constitutes an independent form of claims 10 and 11. New independent claims 128, 133, and 137 constitute an independent form of claims 58, 65 and 78.

In view of the above amendments and remarks it is respectfully submitted that amended claims 1, 4 and 6, claims 7-18, amended claims 19, 21 and 23, claims 24-49, amended claim 50, claim 53, amended claim 54, claims 56 and 57, amended claim 58, claim 59, amended claims 60 and 61, claims 63 and 64, amended claim 65, claim 66, amended claims 69, 70 and 71, claims 72, 73, 75, 76 and 77, amended claim 78, claim 79, amended claims 82, 83 and 84, claims 86, 87, and 89-93, and new claims 94-151

are now in condition for allowance. Prompt notice of allowance is respectfully and earnestly solicited.

Respectfully submitted,

A handwritten signature in cursive script, reading "Martin D. Moynihan", written in dark ink.

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Date: November 22, 2005

Encl.:

Extension of time (one month);

Additional Claim Fee